UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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BRETT SCOVIL, Plaintiff, v. MEDTRONIC INCORPORATED, MEDTRONIC SOFAMOR DANEK USA INCORPORATED, and MEDTRONIC VERTELINK INCORPORATED, Defendants.	Case No. 2:14-CV-00213-APG-VCF **ORDER** (DKT. #51)

Plaintiff Brett Scovil alleges he suffered when his physicians used the Infuse Bone Graft and LT-Cage ("Infuse") device during his back surgery. Scovil contends his physicians used the device in a way not approved by the Food and Drug Administration ("FDA"), which he refers to as "off-label" use. Scovil alleges his physicians did so because defendants falsely promoted that physicians could safely and effectively use Infuse off-label. He therefore asserts various claims against defendants Medtronic Incorporated, Medtronic Sofamor Danek USA Incorporated, and Medtronic Vertelink Incorporated (together, "Medtronic") for their conduct in promoting off-label use of the device as safe and effective.

Scovil initially brought suit in Arizona with his brother, Leigh Scovil, who also underwent back surgery with the Infuse device. (Dkt. #1.) The United States District Court for the District of Arizona dismissed the plaintiffs' manufacturing defect, design defect, failure to warn, and strict liability claims as preempted by the Food, Drug, and Cosmetic Act ("FDCA"). (Dkt. #30 at 15-17, 20.) The court also found their negligence claim was preempted to the extent it was based on "researching, manufacturing, selling, labeling, testing, distributing, and analyzing" Infuse, but the court ruled their negligence, fraud, and intentional misrepresentation claims were not preempted to the extent they were based on defendants' marketing of Infuse. (*Id.* at 17-19.) The court also found the fraud and intentional misrepresentations claims were pled with the requisite

particularity. (*Id.* at 18-19.) The court declined to find the unfair competition claim was preempted, but the court noted the claim potentially lacked legal merit. (*Id.* at 19 & n.14.) Finally, the court dismissed claims for breach of express and implied warranties because it found Medtronic conspicuously disclaimed all warranties, and such disclaimers are valid under Arizona law. (*Id.* at 20.) The court then granted Medtronic's motion to sever the two plaintiffs' claims and transferred Brett Scovil's case to this court. (*Id.* at 20-21.)

After the transfer, the parties agreed that Scovil would file an amended complaint. (Dkt. #42.) Scovil's amended complaint asserts claims against Medtronic for manufacturing defect, failure to warn, negligence, fraud, intentional misrepresentation, Nevada unfair competition, and breach of express and implied warranties. (Dkt. #43.) Medtronic again moves to dismiss each of these claims on various grounds.

I. Background

Medtronic manufactures, promotes, and markets the Infuse device, which is used by surgeons in back surgeries to cure back pain.[1] (Dkt. #43 at 2-4.) Infuse consists of two components that are sold in separate packages but are meant to be used as a single device. (*Id.* at 2, 9.) The first component is a protein that stimulates bone growth, known as recombinant human bone morphogenetic protein-2, that is placed on a collagen sponge. (*Id.* at 2, 8.) The second component is a metal cage that acts as a scaffold to hold the sponge. (*Id.* at 2.)

Infuse was classified as a Class III device under the FDCA. (*Id.* at 5.) Class III devices pose the greatest risk of death or injury and includes implantable surgical devices such as Infuse. (*Id.*); *see also* 21 U.S.C. § 360c(a)(1)(C). Because Infuse is a Class III device, Medtronic was required to obtain premarket approval from the FDA prior to selling it on the market. (Dkt. #43 at 5-6); *see also* 21 U.S.C. § 360c(a)(1)(C). The premarket approval process is designed to provide the FDA with reasonable assurance that the device is safe and effective for its intended use. (Dkt. #43 at 6); *see also* 21 U.S.C. § 360c(a)(1)(C). During this process, the FDA determines the

[1] The factual recitation is derived from the complaint's allegations, which I take as true for purposes of resolving Medtronic's motion to dismiss. *See Williams v. Gerber Prods. Co.*, 552 F.3d 934, 937 (9th Cir. 2008).

proper labeling for the device's intended uses. (Dkt. #43 at 6); *see also* 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A). A manufacturer is not permitted to market the device until it has FDA approval and once approval is obtained, the manufacturer cannot promote the device for uses that have not been approved by the FDA. (Dkt. #43 at 6); *see also* 21 U.S.C. § 360e; 21 C.F.R. § 814.80. Following approval, the manufacturer is under a continuing duty to report to the FDA any information that reasonably suggests the device caused or contributed to death or serious injury. (Dkt. #43 at 6); *see also* 21 C.F.R. § 803.50(a). The FDA granted premarket approval to Infuse on July 2, 2002 for a limited use where both components must be used together in an anterior lumbar interbody fusion procedure involving a single-level fusion in the L4-S1 region. (Dkt. #43 at 6, 9-10.)

According to Scovil, after approval, Medtronic failed to advise the FDA of dangers related to Infuse. (*Id.* at 6.) Scovil contends the protein can lead to excessive bone growth and related complications. (*Id.* at 11.) Scovil alleges Medtronic knowingly failed to report adverse events to the FDA as required. (*Id.* at 18-19.)

Additionally, Scovil alleges Medtronic engaged in a concerted campaign to promote uses of Infuse not approved by the FDA. He alleges this campaign included false representations about the safety of off-label uses of the device or its components. (*Id.* at 6.) For example, Scovil alleges Medtronic promoted Infuse as safe to use in back surgery procedures other than the anterior lumbar interbody fusion procedure. (*Id.* at 10-11.) As evidence of this marketing scheme, Scovil alleges Medtronic sales representatives and consultants received a booklet containing information about the volume and dosage of the protein to be used in off-label applications. (*Id.* at 17.) Additionally, Scovil asserts Medtronic developed a CD series that included information on off-label procedures and sponsored a training program that showed physicians how to perform these off-label uses. (*Id.*)

Scovil contends Medtronic made millions of dollars in undisclosed payments to certain doctors, whom Scovil refers to as "Key Opinion Leaders," to publish articles in medical journals, deliver presentations, and appear at consulting engagements to promote off-label uses of Infuse.

(*Id.* at 15, 17-18.) Specifically, Scovil asserts Dr. Thomas A. Zbeblick co-authored preliminary studies of Infuse without disclosing he received millions of dollars from Medtronic. (*Id.* at 15.) Scovil identifies several other doctors by name who allegedly received millions of dollars from Medtronic. (*Id.*) According to the amended complaint, sales of the protein greatly exceeded sales of the separately-packaged metal cage even though the devices were supposed to be used together, demonstrating substantial off-label use as a result of Medtronic's marketing. (*Id.* at 13.)

Scovil underwent back surgery on October 24, 2006. (Dkt. #43 at 24.) Scovil's surgeons performed a two-level (L4-5 and L5-S1) anterior lumbar interbody fusion procedure using only the Infuse Bone Graft component without the LT-Cage. (*Id.* at 24.) The surgeons' use of the device in this fashion was off-label because they used it at multiple vertebra levels and they did not use the LT-Cage. (*Id.*) Following the surgery, Scovil suffered severe back pain. (*Id.*) In the spring of 2013, Scovil's doctor advised him that his back pain was the result of nerve impingement from bony overgrowth caused by the Infuse Bone Graft. (*Id.*) According to Scovil, his surgeons used Infuse off-label due to Medtronic's promotion campaign and because they were unaware of the risks associated with off-label use. (*Id.* at 23-24; *see also id.* at 17.)

In his Amended Complaint, Scovil asserts claims for manufacturing defect (count one), failure to warn (count two), negligence (count four),[2] fraud (count five), intentional misrepresentation (count six), Nevada Unfair Competition Law (count seven), and breach of express and implied warranties (count eight). Medtronic moves to dismiss, arguing Scovil inappropriately re-pleaded the manufacturing defect, failure to warn, and negligence claims even though those claims previously were dismissed in whole or in part. Medtronic also argues I should reconsider whether Scovil pleaded his fraud and intentional misrepresentation claims with particularity. Medtronic contends I should dismiss the unfair competition claim because Nevada does not have an "Unfair Competition Law." Finally, Medtronic argues I should dismiss Scovil's breach of warranty claims because Nevada would give effect to Medtronic's conspicuous disclaimer of warranties.

[2] The Amended Complaint does not contain a cause of action labeled as count three.

Scovil responds that he has clarified his manufacturing defect and failure to warn claims such that they no longer are preempted. Scovil contends his negligence, fraud, and intentional misrepresentation claims are not preempted because they are based on Medtronic's false representations made during the promotion of off-label uses of Infuse. Scovil also argues the District of Arizona already held he adequately pleaded his fraud-based claims with the requisite particularity. Finally, Scovil asserts that his breach of express warranty claim survives because, under Nevada law, Medtronic's express warranties about Infuse's safety in off-label uses override a general disclaimer.

II. Discussion

In considering a motion to dismiss, "all well-pleaded allegations of material fact are taken as true and construed in a light most favorable to the non-moving party." *Wyler Summit P'ship v. Turner Broad. Sys., Inc.*, 135 F.3d 658, 661 (9th Cir. 1998). However, I do not necessarily assume the truth of legal conclusions merely because they are cast in the form of factual allegations in the plaintiff's complaint. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994). A plaintiff must make sufficient factual allegations to establish a plausible entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Such allegations must amount to "more than labels and conclusions, [or] a formulaic recitation of the elements of a cause of action." *Id.* at 555.

Portions of Medtronic's motion seek reconsideration of the District of Arizona's prior order in this case. Unless the court expressly enters final judgment, the court's orders are "subject to reopening at the discretion of the district judge." *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 12 (1983) (citing Fed. R. Civ. P. 54(b)). "Reconsideration is appropriate if the district court (1) is presented with newly discovered evidence, (2) committed clear error or the initial decision was manifestly unjust, or (3) if there is an intervening change in controlling law." *Sch. Dist. No. 1J, Multnomah Cnty., Or. v. ACandS, Inc.*, 5 F.3d 1255, 1263 (9th Cir. 1993). A district court also may reconsider its decision if "other, highly unusual, circumstances" warrant it. *Id.*

A. Manufacturing Defect - Count One

Scovil's original complaint contained a manufacturing defect claim. (Dkt. #1 at 32.) The District of Arizona ruled this claim was preempted by the FDCA because Medtronic "did not violate any federal law concerning its manufacturing process, and finding that the process was unsafe would necessarily undermine the FDA's finding that the benefits of its manufacturing process for on-label uses outweighed the risks presented by off-label uses." (Dkt. #30 at 16.) Count one of Scovil's amended complaint alleges that the "Infuse drug implanted into [Scovil] was defective as evidenced by its failure to comply with the manufacturing specifications required" by the FDA through premarket approval. (Dkt. #43 at 25.) Additionally, Scovil alleges Medtronic "failed to manufacture the specific Infuse Device [Scovil] received in accordance with the FDA-approved manufacturing process and specifications." (*Id.*) Scovil alleges the device he received "differs from Infuse devices that were manufactured in accordance with the FDA's pre-market approval," and "the specific Infuse [he] received contained a defect and was unreasonably dangerous." (*Id.*)

Medtronic moves to dismiss this claim, arguing Scovil improperly reasserted it. Medtronic also argues that to the extent Scovil is now attempting to assert his particular Infuse device was defective because it was not manufactured in accordance with the FDA-approved manufacturing process, he has not adequately alleged what about the Infuse used in his procedure was defective, how the defect resulted from a deviation from the approved manufacturing process, or what federal requirement Medtronic failed to satisfy in manufacturing the device used in Scovil's procedure. Scovil responds that he is not reasserting the same claim the District of Arizona found preempted. Rather, he is clarifying that his manufacturing defect claim is based on a theory that Medtronic failed to manufacture the Infuse device he received in accordance with the FDA-approved manufacturing process.

To allege a strict products liability claim, a plaintiff must allege that: "1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury." *Fyssakis v. Knight Equip. Corp.*,

826 P.2d 570, 571 (Nev. 1992). The plaintiff must allege facts supporting each of these elements to plead a plausible entitlement to relief. *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1143-45 (9th Cir. 2012) (holding the plaintiff adequately alleged facts identifying the design defect and a safety hazard but the plaintiff did not allege a causal connection between the alleged defect and the safety hazard).

Scovil has not alleged facts plausibly showing a manufacturing defect. Scovil has not alleged any facts regarding a defect in the Infuse device used in his procedure, how the manufacturing process for his device differed from the FDA-approved process, or how any such defect caused his injury. Scovil's factual allegations state it was the manner in which his surgeons used the Infuse, not a manufacturing defect in the particular device, that led to his injuries. Scovil's conclusory allegations tracking the elements of a manufacturing defect claim, with no pertinent facts in support, are insufficient. In response to Medtronic's motion, Scovil has not identified any additional facts he could or would allege to cure these pleading deficiencies, nor does he request leave to amend this claim. I therefore dismiss Scovil's manufacturing defect claim with prejudice.

B. Failure to Warn - Count Two

Scovil's original complaint contained a failure to warn claim. (Dkt. #1 at 33.) The District of Arizona held the claim was preempted because it would require Medtronic to give additional warnings not required by the FDA. (Dkt. #30 at 17.) Scovil has added new allegations that Medtronic failed to report adverse events to the FDA as required. Count two of the amended complaint alleges Medtronic was under a continuing duty to report adverse events to the FDA. (Dkt. #43 at 26.) Scovil alleges Medtronic failed to report adverse events to the FDA as required, thereby preventing his surgeons from learning of the dangers associated with off-label use. (*Id.*)

Medtronic moves to dismiss this claim for two reasons. First, Medtronic argues Scovil has not alleged sufficient supporting facts. Second, Medtronic also argues that even if this claim is sufficiently pleaded, it is impliedly preempted because it attempts to enforce the Medical Devices Amendments ("MDA") to the FDCA through private litigation. Scovil responds that this

claim is adequately pleaded, and that the claim is not preempted because he alleges Medtronic violated federal law and he bases his claim on a parallel duty to report defects under state law. Scovil contends the Ninth Circuit previously held a similar claim was not preempted.

1. Adequate Allegations

Scovil alleges Medtronic had a duty to warn about the dangers associated with off-label use of Infuse, including a continuing duty to report adverse events to the FDA. (Dkt. #43 at 26.) Scovil alleges that before his surgery, Medtronic "failed to provide medical device reports to the FDA . . . concerning problems with off-label Infuse use." (*Id.*) He further alleges Medtronic's failure to do so prevented Scovil and his surgeons, who allegedly were unaware of the risks associated with off-label use of Infuse, "from learning of the dangers of using Infuse in off-label procedures." (*Id.*; *see also id.* at 13-14, 24.) The amended complaint also alleges that once the FDA learned of adverse outcomes, it took regulatory action, including issuing a public health notification and declining to approve a higher strength version of Infuse. (*Id.* at 13.) Scovil alleges Medtronic's failures "proximately caused" his injuries. (*Id.* at 26.)

Viewing these allegations and all reasonable inferences in Scovil's favor, he has alleged a plausible claim for relief. Scovil has alleged non-conclusory allegations that Medtronic had a duty to report adverse events to the FDA; that it failed to do so before Scovil's surgery; that had it done so, the FDA would have taken action to warn the public about additional adverse events; and that once Scovil's physicians received further information, they would not have conducted the off-label procedure. Whether Scovil will be able to prove his claim is not before me at the dismissal stage, nor is Medtronic's factual quarrel with whether it actually failed to report adverse events to the FDA or whether the FDA would have issued warnings had the FDA been aware of additional adverse events. I therefore deny Medtronic's motion to dismiss on this ground.

2. Preemption

A state law tort claim may be expressly or impliedly preempted by the MDA. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The MDA contains an express preemption clause:

> Except as provided in subsection (b)[3] of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); *see also* 21 C.F.R. § 808.1(d)(2). By its plain language, the MDA expressly preempts "only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law." *Riegel*, 552 U.S. at 321. Thus, to determine if a claim is expressly preempted, I first determine whether the federal government "has established requirements applicable to" the device in question. *Id.* at 321. The premarket approval process constitutes federal requirements applicable to Infuse, and thus the first element of the express preemption test is satisfied. *See id.* at 322-23. I thus must determine whether the asserted state law claims are based on Nevada requirements that are different from or in addition to those federal requirements. *See id.* at 321-22.

Implied preemption, on the other hand, occurs when Congress occupies the field of a regulated area (field preemption) or when state requirements conflict with federal requirements (conflict preemption). *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1230 (9th Cir. 2013) (en banc). The FDA and MDA do not field preempt state law tort claims. *Id.* at 1231. However, the FDA and the MDA may conflict preempt state tort claims if the state law "actually conflicts with a federal requirement, making impossible compliance with both requirements . . . or when a state requirement stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (quotation and internal citations omitted). For example, the FDCA provides the FDA "a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Id.* at 353. Thus, allowing a state law tort claim based on fraud on the FDA during the premarket approval process would "inevitably conflict with the

[3] Subsection (b) does not apply.

FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and thus was impliedly preempted. *Id.* at 350, 353. Additionally, because Congress intended the MDA to be enforced only by the federal government, to avoid implied preemption, the plaintiff's state law claims must arise from independent state law duties that do not "exist solely by virtue of the FDCA . . . requirements." *Id.* at 352-53.

In sum, there is a "narrow gap through which a state-law claim must fit to escape preemption by the FDCA." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quotation omitted). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* (quotation omitted, emphasis in original).

The Ninth Circuit has held that a state law tort claim alleging the defendant failed to report adverse events to the FDA as required was not preempted where that same conduct violated state law imposing a duty on manufacturers to use reasonable care to warn about an unsafe product. In *Stengel*, the plaintiff made the same failure to warn argument Scovil makes here, but in relation to a different Medtronic medical device. 704 F.3d at 1226, 1232-33. The Ninth Circuit held this claim was not expressly preempted because Arizona law imposed on manufacturers a duty to warn about known risks associated with a product, and this duty paralleled the federal duty imposed by the MDA to report known adverse events to the FDA. *Id.* at 1233. The state law tort claim was not impliedly preempted because it depended on the independent state law duty rather than on the federal statutory reporting requirements. *Id.* The Ninth Circuit relied on Arizona law that imposed on manufacturers a general continuing duty to warn of dangers. *Id.* The Ninth Circuit also stated that "[i]f a more precise parallel were necessary," Arizona law provides that a manufacturer may satisfy its duty if it warns a third party and "given the nature of the warning and the relationship of the third party, there is reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* (quotation omitted).

Medtronic's argument that Scovil's failure to warn claim is impliedly preempted is foreclosed by *Stengel*. Scovil has asserted the same claim as the *Stengel* plaintiff based on Medtronic's alleged failure to report adverse events to the FDA as required by federal law. Like Arizona, Nevada law contains a parallel requirement because it imposes a continuing duty on manufacturers to warn of defects in their products. *See Wyeth v. Rowatt*, 244 P.3d 765, 780 (Nev. 2010) (en banc) (stating that "if a drug manufacturer knows, or has reason to know, of increased dangers that are not already identified in its drug's label, compliance with the FDA's minimal standard may not satisfy its duty to warn," and the manufacturer's campaign of misinformation regarding the drug's safety supported punitive damages); *Lewis v. Sea Ray Boats, Inc.*, 65 P.3d 245, 249 (Nev. 2003) (en banc) (stating a manufacturer has a duty to warn about the dangers that may result from a product's "use or foreseeable misuse" (quotation omitted)).[4] Thus, under *Stengel*, Scovil's claim is not preempted.

An analysis of the "narrow gap" through which Scovil's claim must fit to avoid preemption confirms *Stengel*'s conclusion. Scovil's claim alleges a violation of federal law based on Medtronic's alleged failure to report adverse events to the FDA (and his claim therefore is not expressly preempted) but he is suing Medtronic because that conduct violates parallel state law duties to warn (and his claim therefore is not impliedly preempted).

Medtronic relies on out-of-circuit authority to argue I nevertheless should find this claim preempted, but I am bound to apply Ninth Circuit law. *Hart v. Massanari*, 266 F.3d 1155, 1170 (9th Cir. 2001). Accordingly, I will not dismiss Scovil's failure to warn claim as preempted.

C. Negligence - Count Four

Scovil's original complaint contained a negligence claim. (Dkt. #1 at 34-37.) The District of Arizona held that the allegations in the original complaint relating to "researching, manufacturing, selling, labeling, testing, distributing, and analyzing" Infuse were preempted because the FDA premarket approval process expressly covers these areas and by granting

[4] *Cf. Klasch v. Walgreen Co.*, 264 P.3d 1155, 1160 (Nev. 2011) (en banc) (holding that when a pharmacist knows of a customer-specific risk, the pharmacist "has a duty to warn the customer or to notify the prescribing doctor of the customer-specific risk").

premarket approval, the FDA necessarily determined Medtronic was not negligent in carrying out these functions. (Dkt. #30 at 17-18.) However, the District of Arizona found the allegations that Medtronic negligently merchandised, advertised, and promoted Infuse were not preempted because off-label promotion violates federal law (and thus is not expressly preempted) but Scovil's claim is based on state negligence law (and thus not impliedly preempted). (*Id.* at 18.) Count four of the amended complaint contains similar allegations that Medtronic was negligent in "researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing" Infuse. (Dkt. #43 at 27.)

Medtronic moves to dismiss this claim, arguing Scovil improperly re-pleaded the claim in its entirety even though the District of Arizona found certain aspects of the claim were preempted. Medtronic also argues I should reconsider the District of Arizona's decision that the marketing aspects of this claim are not impliedly preempted based on other cases post-dating the District of Arizona's order. Those cases have held that a duty to refrain from off-label promotion arises solely from federal law, with no state law corollary. Scovil responds by arguing his negligent marketing claim is not preempted because he seeks to enforce a parallel state law duty of a manufacturer to not market its product for uses it knows or should know are not safe.

Scovil does not defend his negligence claim to the extent it is based on "researching, manufacturing, selling, labeling, testing, distributing, and analyzing" Infuse. I agree with the District of Arizona's reasoning and decision that Scovil's negligence claim based on these allegations is preempted. Scovil's negligence claim is therefore dismissed with prejudice to the extent it is based on "researching, manufacturing, selling, labeling, testing, distributing, and analyzing" Infuse.

However, reconsideration of the District of Arizona's preemption decision with respect to Scovil's negligent marketing claim is not warranted. Medtronic has not identified any newly discovered evidence nor an intervening change in controlling law that would support reconsideration. The District of Arizona's decision was not clearly erroneous or manifestly

unjust. Even if I reconsidered the District of Arizona's preemption decision, Scovil's negligent marketing claim is not preempted.

Pursuant to FDA regulations, "[a] device may not be . . . advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; *see also Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812, 815, 2010 WL 547506, at *2 (9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA." (citing 21 U.S.C. § 331)). Federal law thus prohibits marketing of a Class III device that negligently promotes an off-label use as safe and effective when in fact it is not. Consequently, Scovil's negligence claim is not expressly preempted because it does not impose a requirement different from or in addition to the federal requirement. Scovil's claim is not impliedly preempted because he bases his claim on state negligence law, not on the violation of federal law. *See Eidson v. Medtronic*, --- F. Supp. 2d ----, 2014 WL 1996024, *17 (N.D. Cal. 2014); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 705 (S.D. Tex. 2014). I therefore will not dismiss Scovil's negligence claim to the extent it is based on negligently marketing off-label uses of Infuse as safe and effective.

D. Fraudulent and Intentional Misrepresentation - Counts Five & Six

The original complaint alleged fraudulent and intentional misrepresentations. (Dkt. #1 at 38-42.) The District of Arizona ruled these claims were not expressly preempted because they paralleled the federal prohibition of misleading off-label promotion and they were not impliedly preempted because they are based on traditional state common law. (Dkt. #30 at 18.) The District of Arizona also found the claims were pleaded with sufficient particularity. (*Id.* at 19.) Counts five and six allege Medtronic knowingly concealed adverse information and knowingly provided inaccurate or misleading information regarding the safety and effectiveness of Infuse's off-label uses. (Dkt. #43 at 29-32.) According to the amended complaint, Medtronic knew off-label use of Infuse could lead to serious adverse events but continued to promote off-label use as safe and effective through its sales representatives and Key Opinion Leaders. (*Id.*) Scovil alleges his

medical providers relied on these representations and omissions and had they known of the risks, they would not have used Infuse off-label. (*Id.* at 31.)

Medtronic requests I reconsider whether these claims are impliedly preempted. Medtronic argues that the concept of off-label use derives from the FDCA and has no independent meaning in Nevada law. Medtronic also contends I should reconsider whether these claims are adequately pleaded.

Reconsideration of the District of Arizona's rulings with respect to these claims is not warranted. Medtronic has not identified any newly discovered evidence or an intervening change in controlling law that would support reconsideration of either the preemption decision or whether the claim was alleged with the requisite particularity. Additionally, the District of Arizona's decision was not clearly erroneous or manifestly unjust. Even if I reconsidered the District of Arizona's preemption decision, dismissal on this basis is not warranted for the same reasons that the negligent marketing claim is not preempted. The fraudulent and intentional misrepresentation claims are not expressly preempted because federal law prohibits false promotion of a device's off-label uses and Nevada law imposes a parallel requirement not to engage in fraudulent misrepresentations that is not different from, or in addition to, the federal requirement. Further, the claims are not impliedly preempted because they find their source in state common law regarding misrepresentations and fraud and are not based on the mere fact that Medtronic engaged in off-label promotion. I therefore will deny the motion to dismiss as to these claims.

E. Nevada Unfair Competition Law - Count Seven

Count seven of the amended complaint alleges Medtronic violated the "Nevada Unfair Competition Law" by marketing Infuse in a misleading manner. (Dkt. #43 at 33-34.) The original complaint contained a similar claim under Arizona unfair competition law. (Dkt. #1 at 43-44.) The District of Arizona declined to dismiss this claim because it found Medtronic had mischaracterized the plaintiffs' claim and thus the argument Medtronic made in support of dismissal was flawed. (Dkt. #30 at 19-20.) However, the District of Arizona noted that it was

"doubtful" the plaintiffs could succeed on this claim because it required proof of interference with the plaintiffs' ability to conduct business. (*Id.* at 20 n.14.)

Medtronic moves to dismiss this claim because it is invalid under Arizona law for the reasons stated in the prior order. Medtronic also argues there is no "Unfair Competition Law" in Nevada and thus I should dismiss this claim with prejudice. Scovil has not responded to this portion of Medtronic's motion and he therefore consents to dismissal of this claim. LR 7-2(d). He has not clarified the basis for this claim nor has he requested leave to amend it. I dismiss this claim with prejudice.

F. Breach of Express and Implied Warranties - Count Eight

Count eight alleges Medtronic's marketing campaign expressly and impliedly warranted to physicians, the medical community, and the general public that off-label use of Infuse was safe and effective. (Dkt. #43 at 35-36.) According to the amended complaint, Scovil's doctors relied on these express and implied warranties. (*Id.* at 35.) Scovil alleges Medtronic's marketing campaign to promote Infuse's off-label uses as safe and effective overrides the warranty disclaimer on the Infuse label. (*Id.* at 35-36.) The original complaint contained a similar claim but did not allege that the express and implied representations should override the warranty disclaimer on the label. (Dkt. #1 at 44-45.) The District of Arizona dismissed this claim because Arizona law enforces conspicuous warranty disclaimers. (Dkt. #30 at 20.)

Medtronic moves to dismiss this claim, arguing Nevada gives effect to conspicuous warranty disclaimers and Nevada does not override those disclaimers in favor of expressions of warranties outside the parties' contract. Medtronic contends its disclaimer was conspicuous and cannot be undone by the nonspecific warranties alleged in the amended complaint. Medtronic also argues this claim is preempted because for Scovil to prevail, a jury would have to find that Infuse was not safe and effective and that finding would conflict with the FDA's premarket approval decision.

Scovil responds that under Nevada law, a warranty disclaimer in a form contract cannot disclaim express warranties that form part of the basis of the parties' bargain. Scovil also argues

Nevada has adopted the Uniform Commercial Code ("UCC") and pursuant to certain relevant UCC provisions, Medtronic cannot induce the purchase of its device with express warranties and then attempt to disclaim those warranties. Scovil contends he avoids express preemption because he alleges Medtronic violated federal law through its promotion of off-label use and Nevada imposes a parallel duty. He argues his claim is not impliedly preempted because it rests on state law regarding breach of a warranty.

Under Nevada's UCC, "there is an implied warranty that a good is merchantable and suitable for the particular purpose for which it is sold." *Vacation Vill., Inc. v. Hitachi Am., Ltd.*, 874 P.2d 744, 747 (Nev. 1994) (citing Nev. Rev. Stat. §§ 104.2314-.2315). A manufacturer may disclaim these implied warranties only through specific and conspicuous written language. Nev. Rev. Stat. §§ 104.2316(2), (3)(a). A conspicuous disclaimer "exclude[s] warranties, if any, outside the contract." *Sierra Creek Ranch, Inc. v. J.I. Case*, 634 P.2d 458, 460 (Nev. 1981); *see also Bill Stremmel Motors, Inc. v. IDS Leasing Corp.*, 514 P.2d 654, 656 (Nev. 1973); Nev. Rev. Stat. § 104.2316 cmt. 2 ("The seller is protected under this Article against false allegations of oral warranties by its provisions on parol and extrinsic evidence . . . .").

However, a form disclaimer will not be effective to exclude express written warranties. *Sierra Diesel Injection Serv., Inc. v. Burroughs Corp., Inc.*, 890 F.2d 108, 113 (9th Cir. 1989) (applying Nevada law and stating that "when an express warranty is read together with a warranty disclaimer, the express warranty is given effect over the disclaimer"); Nev. Rev. Stat. § 104.2316(1) & cmt. 1 (stating the UCC "protect[s] a buyer from unexpected and unbargained language of disclaimer by denying effect to such language when inconsistent with language of express warranty and permitting the exclusion of implied warranties only by conspicuous language or other circumstances which protect the buyer from surprise"); Nev. Rev. Stat. § 104.2313 cmt. 1 ("'Express' warranties rest on 'dickered' aspects of the individual bargain, and go so clearly to the essence of that bargain that words of disclaimer in a form are repugnant to the basic dickered terms."). An express warranty may be created through "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the

basis of the bargain." *Id.* § 104.2313(1)(a). Such an affirmation or promise "creates an express warranty that the goods shall conform to the affirmation or promise." *Id.* The seller need not use the words "warrant" or "guarantee" and the seller need not specifically intend to make a warranty. *Id.* § 104.2313(2). However, "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id.*

Here, Scovil does not dispute that Medtronic disclaimed implied warranties relating to Infuse nor does he contend those disclaimers were inconspicuous. In his response to Medtronic's motion, he abandons his implied warranty claim, arguing only that his breach of express warranty claim should survive dismissal. (Dkt. #56 at 15-18.) I therefore dismiss Scovil's claim for breach of implied warranties with prejudice.

As to Scovil's breach of express warranty claim, an express warranty overrides a warranty disclaimer under Nevada law. Consequently, Medtronic cannot disclaim any express warranty it may have made relating to the safety and effectiveness of off-label uses of Infuse. The claim is not expressly or impliedly preempted for the same reasons as the negligence, fraud, and intentional misrepresentation claims. Federal law prohibits false or misleading off-label promotion, and "to the extent that [p]laintiff seeks to impose liability on [d]efendants for voluntarily making misleading warranties outside the label, [p]laintiff is not imposing any requirement different from or additional to what federal law already requires." *Houston*, 957 F. Supp. 2d at 1181. "In other words, to avoid state law liability on this claim, [d]efendants need only to refrain from making misleading warranties, which adds no burden beyond what federal law already imposes." *Id.* For this same reason, a jury would not have to disagree with the FDA's findings regarding Infuse's safety and effectiveness to find in Scovil's favor on this claim. Rather, through the premarket approval process and the prohibition on marketing off-label uses for Class III devices, the FDA already concluded that warranting off-label use of Infuse as safe and effective through off-label promotion was prohibited. The claim is not impliedly preempted because it is based on traditional state law regarding breach of warranty. *See id.*

To state a breach of warranty claim under Nevada law, a plaintiff must allege "that a warranty existed, the defendant breached the warranty, and the defendant's breach was the proximate cause of the loss sustained." *Nevada Contract Servs., Inc. v. Squirrel Cos., Inc.*, 68 P.3d 896, 899 (Nev. 2003). Scovil alleges Medtronic expressly warranted in journal articles and advertising, and through sales representatives and Key Opinion Leaders, that off-label use of Infuse was safe and effective. (Dkt. #43 at 35.) However, he does not allege facts regarding what specific affirmations of fact or promises Medtronic made to him or to his physicians or that those specific affirmations or promises became part of the basis of the bargain. *See, e.g.*, *Houston*, 957 F. Supp. 2d at 1181; *Arthur v. Medtronic, Inc.*, No. 4:14-CV-52 (CEJ), 2014 WL 3894365, at *8 (E.D. Mo. Aug. 11, 2014) (slip copy) (same and collecting cases). I therefore dismiss without prejudice Scovil's breach of express warranty claim.

III. Conclusion

IT IS THEREFORE ORDERED that defendants' motion to dismiss (Dkt. #51) is GRANTED in part and DENIED in part. Plaintiff Brett Scovil's claims for manufacturing defect (count one), negligence based on allegations other than marketing (part of count four), unfair competition (count seven), and breach of implied warranty (part of count eight) are dismissed with prejudice. Scovil's claim for breach of express warranty (part of count eight) is dismissed without prejudice. Defendants' motion is denied in all other respects.

DATED this 2nd day of March, 2015.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE